Proposed Addition to
Division of Medical Assistance N.C. Prior Authorization Program
Growth Hormones

DRAFT

Therapeutic Class Code: P1A, P7A

Therapeutic Class Description: Growth Hormones

Medication	Generic Code Number(s)	National Drug Code(s)
Genotropin	63351, 10554, 63408	
Genotropin Miniquick products	21450, 21451, 21452, 21453, 21454, 50207, 50217, 50177, 50187, 50197	
Humatrope	00575, 25957, 25963, 25969	
Norditropin; Norditropin 15 mg/1.5 ml, Norditropin Nordiflex	24145, 24146, 24147, 63407, 92376, 92386	00169777411
Nutropin, Nutropin Depot; Nutropin AQ 20 mg/2 ml pen CA	25967, 25954, 91404, 91405, 91406, 17475, 33320	50242001902, 50242001966, 50242003249, 50242007201, 50242007202, 50242007203
Omnitrope; Omnitrope 5 mg/1.5 ml CRTG; Omnitrope 10 mg/1.5 ml CRTG	93215, 92366, 92386	
Saizen	~~12767,~~ 23695	44087100502, 54569493000, 44087108801
Tev-Tropin		57844071319, 57844071341
Zorbtive	12767	
Increlex	25465	

Use of Serostim for AIDS wasting syndrome is exempted from this policy and does not require prior approval.

Early and Periodic Screening, Diagnosis and Treatment Provision

Early and Periodic Screening, Diagnosis and Treatment (EPSDT) allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are medically necessary health care services to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service product or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at http://www.ncdhhs.gov/dma/EPSDTprovider.htm.

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Criteria (excludes Zorbtive and Increlex)

A. Adults with growth hormone deficiency:

Coverage is provided in the presence of all the following:

1) Biochemical diagnosis of somatotropin deficiency by means of a negative response to a standard growth hormone (GH) stimulation test
2) This deficiency, either alone or with multiple hormone deficiencies, is a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma
3) Adult patients who were diagnosed with GH deficiency in childhood must have a low level of insulin-like growth factor–1 (IGF-1) after having been off GH therapy for at least 1 month

B. Children with growth hormone deficiency:

Coverage is provided in the presence of all the following:

1) ~~Growth hormone~~GH dysfunction or lack of adequate endogenous ~~growth hormone~~GH documented by any of two provocative tests of less than 10mg/ml
2) Patient's height must be below the third percentile for their age and gender related height
3) Epiphysis confirmed as open in patients greater than 9 years of age

~~A growth response of greater than 4.5 cm/year (pre-pubertal growth phase) or greater than 2.5 cm/year (post-pubertal growth phase) must occur for continuation of coverage.~~

C. Patients with the following conditions (no requirement for growth hormone stimulation testing):

1) Children with craniopharyngiomas
2) Children with multiple pituitary hormone deficiencies (panhypopituitarism) who have abnormal height velocity (height velocity <25th percentile for bone age) and low serum levels of IGF-1 and insulin-like growth factor binding protein–3 (IGFBP-3)
3) Children with abnormal height velocity (height velocity <25th percentile for bone age), low IGF-1/IGFBP-3 levels, and anatomic (MRI) evidence of hypopituitarism (ectopic posterior pituitary bright spot, small or hypoplastic pituitary gland or stalk, or empty sella)
4) Adequately nourished infants or children who have hypoglycemia and low GH response to hypoglycemia and who show other signs of hypopituitarism
5) Children who have received cranial irradiation with a decreased height velocity (height velocity <25th percentile for bone age) who show other evidence of hypopituitarism (one or more additional pituitary hormone deficiencies)

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D. Coverage for a trial of GH therapy is provided for **children with otherwise unexplained short stature** who may pass GH stimulation tests, but who meet all of the following criteria:

1) Height >2.25 standard deviations below mean for age
2) Height velocity <25th percentile for bone age
3) Bone age >2 standard deviations below mean for age
4) Low serum IGF-1/IGFBP-3

E. Coverage is provided in the **absence of documented growth hormone deficiency, stimulation tests, or IGF-1 levels** in the following situations:

1) Patients with Turner's syndrome
2) Children with height less than 3rd percentile for chronologic age with chronic renal insufficiency
3) Patients with Praeder-Willi syndrome
4) Children who were born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) in whom the birth weight and/or length were more than 2 standard deviations below the mean for gestational age, and who fail to show catch-up growth by age 2 (defined as a height velocity below 1 standard deviation score, adjusted for age)

Increlex

Therapy with Increlex (IGF-I) must be reserved for children with growth failure that will not respond to GH therapy: those with GH resistance caused by a mutation in the GH receptor or post-GH receptor signaling pathway, IGF-I gene defects, and individuals with GH gene deletions who have developed neutralizing antibodies to GH. In addition, children with severe short stature may be considered for Increlex therapy if they have failed a trial of GH therapy. Children must have a height less than 3 SDs below the mean, an IGF-I level less than 3 SDs below the mean, and normal or elevated GH levels.

Zorbtive

Therapy with Zorbtive must be reserved for patients with short bowel syndrome.

Continuation of Therapy

Coverage is provided in the presence of all of the following criteria. (Patients with genetic causes of GH deficiency/hypopituitarism and multiple pituitary hormone deficiencies are exempt.)

1) A growth response of greater than 4.5 cm/year (pre-pubertal growth phase) or greater than 2.5 cm/year (post-pubertal growth phase) must occur for continuation of coverage.
2) Minimum yearly IGF-I and/or IGFBP-3 monitoring must be performed, and results must be within age-appropriate ranges.

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Procedures

1. The P&T recommends that a pharmacist handle all prior authorization requests for this therapeutic class.
2. The request must come from the physician's office.
3. Approval length up to one year.
4. Exemption forms will not be accepted for this drug class.

References

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